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ORIGINAL RESEARCH ARTICLE

Evaluation of two rapid commercial assays for detection of *Streptococcus agalactiae* from vaginal samples

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Abstract

Introduction: *Streptococcus agalactiae*, also known as group B streptococci (GBS), is associated with invasive infections in neonates. Identification of GBS vaginal colonization in pregnant women before delivery is essential for treatment with antibiotics to prevent intrapartum vertical transmission to the newborn. This study was designed to evaluate applicability of two rapid real-time PCRs in comparison to standard culture identification.

Material and methods: We compared the Xpert GBS assay, hereafter referred to as Xpert, and GenomEra GBS PCR, hereafter referred to as GenomEra. The standard culture identification consisted of two different agar plates as well as an enrichment broth.

Results: We analyzed vaginal samples of 260 pregnant women; 42 samples were tested GBS-positive by using standard culture as a gold standard, 30 by Xpert, and 37 by GenomEra. Xpert and GenomEra assays performed with sensitivities of 71.4% and 88.1% as well as specificities of 98.6% and 99.1%, respectively. Twelve vaginal samples were false-negative by Xpert and five samples by GenomEra. Interestingly, three negative Xpert results of standard culture-positive samples exhibited high Ct-values indicating the presence of GBS. If higher Ct-values are taken into consideration, the sensitivity of Xpert increases up to 78.6%. Moreover, only three Xpert PCRs had to be repeated, whereas two Genomera were invalid even after repetition and further 15 GenomEra PCRs were repeated because of borderline results or inhibition of the PCR test.

Conclusions: In this study, GenomEra assay performed with a higher sensitivity than the Xpert PCR. On the other hand, the Xpert assay needs less hands-on-time for a sample preparation and requires approximately four-fold less repetitions as compared to the GenomEra assay. This robust performance of the Xpert assay make it applicable as a rapid intrapartum point-of-care test, although a higher sensitivity would be

Abbreviations: CAMP test, Christie-Atkins-Munch-Peterson test; EOGBS, early-onset GBS; GBS, group B streptococci.

desirable. Therefore, culture in the 35–37 week of gestation remains the gold standard to detect vaginal colonization.

KEYWORDS
delivery, GBS, GenomEra, group B streptococci, intrapartum, PCR, point-of-care, pregnancy, *Streptococcus agalactiae*, Xpert

1 | INTRODUCTION

Streptococcus agalactiae, often referred as group B streptococci (GBS), are Gram-positive and β-hemolytic streptococci, which commonly grow in chains and are the sole member of the Lancefield group B. GBS are commensals of human intestinal and genitourinary tracts but can cause severe opportunistic infections. These can affect elderly, immunocompromised and neonates. In fact, GBS is the leading cause of invasive infections in neonates worldwide with about 90.000 infant death estimated by the World Health Organization in 2015.[1] Infection of the newborn may manifest as sepsis, pneumonia or as early-onset disease,[2] whereas meningitis is still a leading manifestation of a late-onset GBS (LOGBS) disease.[3] More than one third of infants who survive GBS meningitis develop neurological impairments.[4]

Ten to thirty percent of pregnant women are colonized with GBS in the US as well as in Europe.[5] Fifty to sixty percent of all newborns of GBS-positive mothers are colonized with GBS during delivery, and 1%–2% of them develop clinical symptoms.[6] After the introduction of antibiotic therapy during delivery for GBS positive women in the US, early-onset GBS (EOGBS) infections decreased from 1.8/1000 livebirth in the 1990s to 0.26/1000 livebirths by 2010[7] and 0.23/1000 livebirths by 2015,[8] which is a reduction of between 86% and 87%.

According to several retrospective studies, most infants with proven EOGBS infections are born to GBS-negative women.[9,10] Indeed, the status of GBS colonization may be transient or periodic.[11,12] Some women are colonized with GBS at the time of labor, but are screened negative at 35–37th week of pregnancy.[9,13] A prospective multicenter cohort study from 2018 found that between late pregnancy screening and labor, GBS colonization changed from negative to positive in 3.2% and from positive to negative in 2.5% of delivering women.[6]

The standard culture for detection of GBS remains the gold standard. However, it takes 1 to 2 days to obtain the results. Recent data, showing that GBS colonization status can change at the time of birth, enforce that other screening methods just before delivery should be sought.[14] PCR assays providing a rapid result may accurately reflect intrapartum GBS colonization. In this study, we compared two rapid PCR assays, Xpert GBS (Cepheid) and GenomEra GBS (Abacus Diagnostica), hereafter referred to as Xpert and GenomEra, with culture as the gold standard. The aim of the study was to evaluate PCR applicability in the hospital setting, especially when a quick answer regarding GBS colonization is needed.

Key message

Two rapid PCR assays for the identification of GBS were compared by standard culture. The Xpert GBS assay performed robustly, although higher sensitivity would have been desirable, suggesting that culture identification remains the gold standard for detecting vaginal colonization.

2 | MATERIAL AND METHODS

2.1 | Study population

Between March and June 2021, a total of 264 pregnant women were included in this study. All patients were admitted to the delivery ward of the University Hospital Zurich, Switzerland, due to impending birth. The patients were screened for GBS by culture, GenomEra and Xpert assays. Four patients were excluded from the study. The reasons for exclusion are as follows: three GenomEra polymerase chain reactions (PCRs) and their repetitions were inhibited and one GenomEra PCR was borderline (culture and Xpert were negative for all 4 patients). Thus, the population considered was 260 patients.

2.2 | Vaginal sample collection

Two vaginal swabs per patient were sampled simultaneously. Sample secretions were collected from the lowest one third of the vagina by rotating the swabs three times ensuring uniform distribution on both swabs. One sample collected with a Copan Transsystem 139C swab (Copan) was analyzed by Xpert immediately after sampling at the delivery room. The second swab collected in Copan eSwab 80490CEA transport medium (Copan), was used for culturing and GenomEra assay, which was performed at the laboratory of the Institute of Medical Microbiology in Zurich.

2.3 | Xpert GBS PCR

The Xpert assay is a real-time PCR for the detection of group B streptococci from vaginal or rectal swabs. The primer and the probe of the PCR amplify a target within a 3'-DNA region adjacent to the CAMP-factor (*cfb*) gene of *S. agalactiae*. The sampling and PCR was performed

by residents who received a detailed introduction to proper specimen collection and PCR performance according to the manufacturer's recommendations. In short, the Copan swab was transferred into the designated chamber of the Xpert cartridge. The cartridge was then loaded into the GeneXpert device. The amplification of the *cfb* gene was defined as positive when the cycle threshold (Ct) was >0 and ≤42. The total runtime of the PCR was approximately 50 minutes or less.

2.4 | GenomEra GBS PCR

The GenomEra assay is performed on the GenomEra CDX system (Abacus Diagnostica), which is a molecular diagnostic analyzer consisting of an integrated thermal cycler and a time-resolved fluorometer. As described in Nielsen et al.,[15] the PCR targets an internal region of the *cfb* gene, which is expected to detect all clinical GBS isolates. According to the manufacturer, the test can be used for vaginal-rectal swab samples collected into Copan eSwab transport medium and from enrichment broth cultures of samples. Here, we applied the first variant using directly the transport medium and followed the manufacturer's instructions. In short, 100 µL of the eSwab medium was transferred to a Z-tube containing 1 mL buffer and glass-beads. The Z-tube was vortexed at full speed for 5 minutes, and 35 µL was carefully pipetted by avoiding air bubble formation to the test chip. The test chip was then loaded to the GenomEra CDX system, and the PCR was started. The runtime takes approximately 50 minutes ending with reporting the result. Results are given as an arbitrary number between −15 to 100, where negative results are from −15 to −4, borderline results from −3 to 3 and positive results from 4 to 100.

2.5 | GBS culture

The remaining eSwab transport medium was used for laboratory culture identification of GBS. The eSwab was vortexed to homogenize the transport medium before plating on Columbia agar containing colistin-nalidixic acid (Columbia CNA agar + 5% sheep blood, bioMérieux) and GBS agar (Brilliance GBS, Thermo Scientific) using a three phase streaking pattern. Both plates were incubated for 18–24 hours at 37°C under aerobic conditions with 5% CO_2, and further incubated for another 24 hours when negative for GBS. All suspect bacteria were identified by matrix-assisted laser desorption/ionization time-of-flight (MALDI-TOF) mass spectrometry (Bruker Daltonics). The number of GBS was estimated by the growth on the GBS agar as follows: growth only on the first fraction corresponded to $<10^4$ CFU/mL, growth on the first and second fraction 10^4–10^5 CFU/mL, and growth on all three fractions $>10^5$ CFU/mL, respectively.

2.6 | Enrichment and CAMP test

In addition to direct culture on agar plates, a selective GBS broth enrichment was performed in a bouillon. This bouillon contained peptone from pancreatic digest of casein (Merck) as a nitrogen source and starch (Merck) as carbon source buffered at pH 7.4 with phosphate and supplemented with horse serum, metronidazole and gentamicin. Two drops of the patient's sample in eSwab transport medium were pipetted into 5 mL GBS broth and incubated for 18–24 h at 37°C. Hereafter, a CAMP (Christie-Atkins-Munch-Peterson) test[16] was applied to phenotypically identify the production of the CAMP factor that enlarges the area of hemolysis formed by the β-hemolysin produced by *Staphylococcus aureus*. In short, a hemolysin-producing strain of *S. aureus* is streaked as single line to sheep-blood agar. Control strains and the enrichment broth culture are streaked in right angle against the streak of *S. aureus*. A positive control of *S. agalactiae* will show the formation of an arrowhead-shaped zone of β-hemolysis at the junction of both organisms, whereas a negative control of *Enterococcus faecalis* will show no formation.

2.7 | Statistical analyses

The sensitivity, specificity, positive and negative predictive values (PPV and NPV) of both GBS assays were calculated with a confidence interval (CI) of 95% using the culture identification as gold standard. Statistical analysis was performed using the online diagnostic test evaluation calculator by MedCalc (http://www.medcalc.org/calc/diagnostic_test.php).

2.8 | Ethics Statement

The clinical study was approved by the Regional Scientific Ethical Committee for the Canton of Zurich, Switzerland (2018-01845) and accepted on July 23, 2019. All participants provided written informed consent.

3 | RESULTS

The clinical characteristics of the study population are shown in Table 1. The mean age of pregnant women was 33 years. A total of 62% of the women were expecting their first child. Gravidity lasted on average 38.4 weeks, with spontaneous delivery of 53.8%, followed by cesarean section with 35% and 11.2% by vacuum extraction.

Forty-two out of 260 patients (16%) were positive by culture, 37 were true-positive by GenomEra, and 30 true-positive by Xpert. The sensitivity of the culture by using CNA and GBS agar was not improved by performing an additional GBS enrichment followed by a CAMP test from the enrichment broth. The simultaneous use of GBS agar, enrichment broth and CNA agar did identify 42 samples with GBS. From these 42 samples, 39 samples showed growth of GBS on GBS agar. The remaining three culture positive samples were positive on CNA agar and were detected by the CAMP test from enriched broth culture. One GBS positive sample was identified only

TABLE 1 Clinical characteristics of the study population, $N = 260$.

Characteristics	Value
Age (years)	33 (21–43)
Gravidity (I)	127 (50%)
Parity (I)	158 (62%)
Weeks of pregnancy at delivery	38.4 (22–41)
Mode of delivery	
Spontaneous delivery	140 (53.8%)
Primary cesarean section	18 (6.9%)
Secondary cesarean section	73 (28.1%)
Vacuum extraction	29 (11.2%)
PPROM	16 (6.3%)
Preterm labor	9 (3.5%)
Sub partu fever	6 (2.3%)
Intra-amniotic infection	9 (3.5%)
Time interval sampling until delivery	
0–7 days	217 (84.8%)
8–28 days	18 (7.0%)
>28 days	25 (9.8%)

Note: Data are number of women (%) or median (range).
Abbreviation: PPROM, preterm premature rupture of membranes.

on CNA agar, but not on GBS agar or in enriched broth. Overall, 40 samples were positive in enriched broth, but only 28 samples were positive on CNA agar.

When the results of both PCR assays were considered together, there was no GBS-negative culture, but a PCR-positive result, as two false-positive GenomEra samples were true-negative with Xpert, and three false-positive Xpert samples were true-negative with GenomEra. Thirty samples were tested positive by culture and by both PCR assays. A total of 15 GenomEra PCRs had to be repeated because of an initial inhibition of the PCR or a technical error, and resulted finally in two positive and 13 negative PCRs. Only three of 260 Xpert assays resulted in an error and needed to be repeated; the results of the repetitions were negative. To minimize bias, negative PCR results were generally not repeated if the culture result was positive as this would have falsely increased the sensitivity of the PCR.

GenomEra identified 37 true-positive and 216 true-negative samples, with 12% (5/42) false-negative and 0.9% (2/218) false-positive samples (Table 2), resulting in a sensitivity of 88.14% (37/42) and a specificity of 99.1% (216/218; Table 3). The culture and the Xpert of the two false-positive patients were negative. The five false-negative GenomEra samples showed only few colonies on GBS agar and were negative on CNA agar. One CAMP test was negative, but GBS did grow on GBS agar.

Among GBS culture-positive samples, 71.4% (30/42) were true-positive using Xpert. The Xpert PCR resulted in a specificity of 98.6% (215/218), with 1.4% (3/218) of the GBS culture-negative samples false-positive (Table 3). The culture and GenomEra were positive for seven of the 12 false-negative Xpert results, whereas for the remaining five culture-positive samples both PCR were negative.

For three of the false-negative Xpert PCRs, the GBS culture showed only few GBS colonies. A detailed analysis of the Xpert results found a high Ct-value >42 for these PCR runs, which is higher than the defined cycle threshold of 42 for a positive result. Here, we decided to override this threshold and to rate these three Xpert results as true-positive including it in a further analysis called "Xpert (reviewed)" (Table 2). This further analysis found 33 true-positive and nine false-negative samples, resulting in an increased sensitivity of 78.6% (33/42; Table 3). The Xpert PCR and its reviewed analysis had a false-negative rate between 29% (12/42) and 21% (9/42), respectively. From the nine false-negative samples, eight samples showed a low GBS colonization rate of $<10^4$ CFU/mL, which was probably below the detection limit of the PCR.

Xpert report Ct-values correlated to the number of bacteria determined by GBS culture (Figure 1). Fourteen samples showed GBS growth $>10^5$ CFU/mL having a median Ct-value of 30.6, 7 samples with GBS growth between 10^4–10^5 CFU/mL with a median Ct of 32.5 and 12 samples with GBS growth $<10^4$ CFU/mL and a median Ct of 35.9. The median Ct-value increased with decreasing GBS load in the sample.

4 | DISCUSSION

Intrapartum antibiotic prophylaxis of the GBS colonized women is a worldwide accepted strategy to prevent EOGBS infections.[9,17] Studies show that universal screening has an advantage in preventing EOGBS disease in comparison to risk based protocols for antibiotic prophylaxis during childbirth.[18] Therefore, cultures of vaginal and/ or rectovaginal sites are obtained during the last trimester of pregnancy, generally between 35 and 37 weeks of gestation and the results are usually valid for the next five to 6 weeks.[17] However, this strategy has some limitations.

The gastrointestinal tract is the natural reservoir for GBS. Simultaneous rectovaginal sampling could increase the sensitivity of GBS detection, but could also increase the number of women given intrapartum antibiotics. To our knowledge, a clinical benefit of combined recto-vaginal sampling has not yet been clarified.[14] However, only vaginal sampling is performed at the University Hospital of Zurich.

A prospective multicenter cohort study from 2018 stated that GBS colonization might change when screening has been performed before the 36th week of pregnancy.[6] When intrapartum culture is taken as reference, sensitivity of antepartum culture decreased when sampling was done before the 36th weeks of pregnancy.[6] The main goal of our study was the evaluation of a PCR assay for the rapid detection of GBS, when labor is anticipated and therefore, a culture is in most cases not fast enough. This was true for most of the patients, among which 69.5% of all sampling was performed at maximum 2 days before delivery (Table 1). About 9.8% of women were sampled more than 4 weeks prior to delivery and, therefore,

TABLE 2 GenomEra and Xpert GBS assays vs standard culture.

	GenomEra vs. culture		Xpert vs. culture		Xpert (reviewed)[a] vs. culture	
	Positive	Negative	Positive	Negative	Positive	Negative
Positive	37	2	30	3	33	3
Negative	5	216	12	215	9	215
Total	260		260		260	

[a]Xpert (reviewed): Negative Xpert results were given as positive, on condition that high Ct-values indicate the presence of GBS.

TABLE 3 Sensitivity, specificity and predictive values for both, GenomEra and Xpert, PCR assays for the detection of *Streptococcus agalactiae* (GBS) with standard culture as the gold standard.

	GenomEra		Xpert		Xpert (reviewed)[a]	
	[%]	(95% CI)	[%]	(95% CI)	[%]	(95% CI)
Sensitivity	88.1	74.4–96.0	71.4	55.4–84.2	78.6	63.2–89.7
Specificity	99.1	96.7–99.9	98.6	96.0–99.7	98.6	96.0–99.7
PPV	94.9	82.3–98.7	90.9	76.2–96.9	91.7	78.0–97.2
NPV	97.7	95.0–99.0	94.7	91.7–96.7	96.0	93.1–97.6

[a]Xpert (reviewed): Negative Xpert result were given as positive, on condition that high Ct-values indicate presence of GBS.

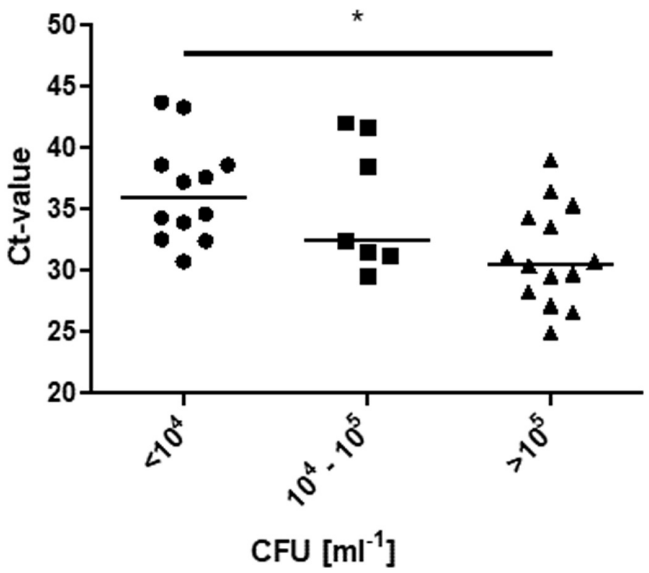

FIGURE 1 Correlation of Xpert Ct-values with CFU (mL) for 35 Xpert results having Ct-values between 24.9 and 44.7. The CFUs of *S. agalactiae* can be grouped into $<10^4$ CFU/mL, 10^4–10^5 CFU/mL and $>10^5$ CFU/mL. The median of Ct, indicated by the bar within each box, increases with decreasing number of GBS in the sample. Statistical significance was determined for CFU values $<10^4$ CFU/mL having a Ct median of 35.9 compared to CFU $>10^5$ CFU/mL with a Ct median of 30.6. Statistical difference was calculated with a Kruskal-Wallis test followed by a Dunn's comparison (*$p < 0.05$).

had a higher risk for an undiagnosed colonization of GBS at the time of delivery. Since the exact time of delivery is difficult to predict, we decided to include all patients undergoing GBS screening in the study for the evaluation of PCR.

In the aforementioned study,[6] 29.7% patients were positive by culture but only 28.2% by Xpert. Here, we found a slightly higher difference between the screening results of GBS culture and Xpert PCR, with a positive rate of 16.2% (42/260) by culture but 11.5% (30/260) by PCR, which is different in 4.6% (12/260). We determined a sensitivity of 71.4% for the Xpert, whereas the former prospective study found a higher sensitivity of 91.5% for the intrapartum PCR.[6] The false-positive rate for the Xpert GBS in our and the referred study is comparable with 1.4% and 1.2%, respectively.

Our study not only compared the detection of GBS by culture and Xpert, but also evaluated an extra PCR technique, namely GenomEra. We found the GenomEra assay to be more sensitive than the Xpert assay, with a sensitivity of 88.1% (37/42) vs 71.4% (30/42), respectively. A more in-depth analysis of the Xpert PCR in terms of reviewing the Ct-values resulted in an about 7% increased sensitivity with 78.6% (33/42). This was achieved by excluding three false-negative PCR results and including Ct-values above 42, which was defined as negative by the manufacturer. When using Ct-values above the manufacturer's cutoff we would recommend a confirmation by conventional GBS culture.

A study from Kolding hospital in Denmark estimated similar sensitivity values for GenomEra and Xpert assays with 91.8%, and 91.7%, respectively,[15] applying standard culture as reference. The Xpert with sensitivity of 71.4% in our population performed less efficiently than for the population of Kolding with 91.7%, but the GenomEra performed with similar sensitivity of 88.1% (Zurich) as compared to 91.8% (Kolding). Sampling, sample preparation and carrying out the PCR in both studies were done in the same way.

In France, GBS screening in a labor ward was evaluated for a study population of 565 pregnant women applying intrapartum Xpert vs intrapartum culture. The sensitivity of the PCR was 84.4%,[19] which is similar to our results. Overall, the total number of invalid results was 77 (13.6%), but a repetition of PCR gained a valid result in 28 cases.[19] In contrast to that, we repeated only

three samples with Xpert (1.2%) and had no invalid PCRs (Table 2). Interestingly, the authors found seven samples with Ct-values >42 that had positive cultures with only few colonies on the agar. After a control of discrepancies in the laboratory, the sensitivity increased to 92.8%,[19] which is close to the value found in a study by Nielsen et al.[15] Consequently, the authors recommend a training of nonspecialized staff is mandatory to reach an acceptable sensitivity for such a bedside test in labor wards.[19]

A disadvantage of the GenomEra assay is that the sample preparation includes a 5-minute lasting step of vigorous shaking with glass beads to get rid of mucus before PCR. Due to that, we decided that this kind of sample preparation is not practicable in the hospital setting when labor has already started. Therefore, this PCR was performed in the diagnostics facility as an alternative for culture, but not as a bedside test. In our hands, 15 Genomera PCRs had to be repeated due to borderline results or inhibition and two PCRs were invalid, even after repeating the assay. On the contrary, the Xpert assay can be performed without an extra sample preparation step and is more robust as compared to the GenomEra assay.

Discrepancies for sensitivity values from different studies[15,19] seem to be population and PCR dependent. Due to the extra sample preparation step of the GenomEra assay, PCR was less affected by mucus than the Xpert assay. Mucus probably affected the Xpert assay resulting in a decreased sensitivity, but not in invalid PCR results, which would explain the discrepancy between both assays in our study. A further study should test whether the Xpert assay yields higher sensitivity by transferring a swab desired for PCR into an eSwab containing a transport medium, as it was the case for the GenomEra PCR.

Mutations in the specific target gene region affecting the PCR can explain discrepancies between both GBS assays. The gene target of the Xpert assay is a region adjacent to the GBS *cfb* gene, whereas the GenomEra target is an internal region of the *cfb* gene.[15] If such mutation occurs only in the primer binding regions of one target, the sensitivity of this assay decreases. So far, other studies comparing different GBS PCRs did not observe discrepancy in sensitivities.[14,15,19] Therefore, we assumed that the decreased sensitivity of the Xpert PCR in our population was more dependent on sample preparation and mucus inhibition than on possible occurrence of mutations. Cepheid appears to be aware of this issue. After completion of our study, the manufacturer announced a new generation of Xpert GBS, which is expected to cover this specific variant by introducing a second gene target.

In addition to the standard culture on GBS agar, a broth enrichment in GBS bouillon was performed, followed by a CAMP test to visualize the CAMP factor on blood agar. The CAMP test did not improve sensitivity of the culture. Even the CAMP test failed the detection of one culture positive sample. *S. agalactiae* was detected on GBS agar with only a few colonies, but a CAMP test of an enriched culture was negative. Interestingly, other streptococci were detected on the agar. We believe that these streptococci overgrow in the enriched culture and inhibit the growth of GBS. Another possibility is given in a study from 2016 describing the rare occurrence of CAMP-negative GBS due to a mutation in the *cfb* gene, encoding the CAMP protein, which was not detected by Xpert or did not show a positive CAMP reaction.[20] The existence of such CAMP-negative GBS would argue that all PCR results should be confirmed by culture identification. However, to our knowledge, such a strain has only been reported once.

There are two aspects which should be noted. First, the sensitivities of the two PCR assays are lower than in other studies, or differently viewed, the positive rate of our culture identification is higher. This means that we appear to have improved the sensitivity of cultural detection of GBS by using three culture media, GBS agar, CNA agar and enrichment broth, simultaneously. The growth of only a few GBS colonies is probably below the detection limit of the PCR, which might explain the high rate of false-negative PCR results. Nevertheless, the risk of GBS-colonized patients not being treated with intrapartum antibiotics is increased by false-negative PCR results, which should be considered by clinicians. Second, the sensitivity of the Xpert PCR is lower compared to the GenomEra PCR. The lower sensitivity of the Xpert assay might be due to the design of the Xpert GBS assay. In that case it would be interesting to evaluate the sensitivity of the updated Xpert GBS version in order to confirm this hypothesis. Another reason for the lower sensitivity might be due to practical experience of the staff in the microbiology laboratory compared to the residents in the delivery ward, as well as that only a few people performed the culture and PCR in the laboratory in this study, whereas the Xpert was used as true point-of-care test by many residents in the hospital setting.

5 | CONCLUSION

In general, we recommend that the culture is performed in the laboratory for GBS screening. However, our study confirmed the suitability of the Xpert PCR as point-of-care test for a rapid intrapartum GBS detection and consequentially antibiotic prophylaxis can be commenced where a standard culture is not possible due to a time deficiency. This assay has a very high specificity, but a lower sensitivity compared to the culture and GenomEra assay. In cases where higher sensitivity of a molecular diagnostic test is required, one should opt for an exact sampling and sample preparation by a specifically trained member of staff. The manufacturer of the Xpert GBS assay has subsequently released an updated version after this study was finalized. It would be interesting to evaluate whether this version performs with a higher sensitivity.

AUTHOR CONTRIBUTIONS

DB, RZ and RZ conceived and designed experiments. HKB wrote the manuscript and performed experiments. AN performed experiments. DB and HKB analyzed the data. DB, HKB, RZ and RZ edited the paper. JB helped to coordinate the sampling. MS wrote the ethic approval.

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CONFLICT OF INTEREST

All authors declare that they have no conflicts of interest.

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